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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/964,120 | 09/25/2001 | Marvin L. Schilling | BWS-00-07 | 9970 |

7590 05/07/2002
BERND W. SANDT
900 Deerfield Court
Midland, MI 48640

EXAMINER

GOLLAMUDI, SHARMILA S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 05/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,120

Applicant(s)

SCHILLING ET AL.

Examiner

Sharmila S. Gollamudi

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-17 are included in the prosecution of this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Ericsson (5773241).

Ericsson discloses the method of preparing bioactive extracts. The method for animal tissue (organs or glands) involves macerating the tissue and adding a solvent containing NaCl, KCl, etc. For extracting proteins and alkaloids, the temperature of distillation should be low in order not to denature the active material. (Note col.4, lines 20-51).

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by JP359088065.

JP teaches the immersing bone or marrow in sodium hypochlorite, adding aqueous solution of lecithin, mixing, grinding, and heating the mixture. The active substance is then dehydrated. (Note abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 02028119 over Ericsson (5773241).

The reference teaches the method of removing an active agent from animal material by pulverizing the tissue, forming a suspension with a solvent, a stabilizer, an antiseptic (phenol), an inorganic salt (potassium chloride), heating the suspension, and obtaining a dried form. (Note abstract).

The reference does not teach the temperature the suspension is heated.

For extracting proteins and alkaloids, the temperature of distillation should be low in order not to denature the active material. (Note col.4, lines 20-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to heat the solution to a temperature that extracts the active substance without inactivating as taught by Ericsson and the active substance yielded JP requires activity for making the vaccine.

Claims 3-4 and 8-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Ericsson (5773241) in view of DD 202800.

As set forth above, Ericsson discloses the method of preparing bioactive extracts. The reference also teaches the method of extracting active agents from plant material. The method involves macerating the plant material and distilling with ethanol (col. 10-25). The reference teaches the plant material to yield essential oils. The reference teaches reducing moisture content to less than 14% and plant material can be

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dried at temperatures of 100-140 degrees F (col.2, lines 46-48). The reference teaches using different solvents for yielding different active substances. For instance, proteins and carbohydrates require water, ethanol, sodium, phosphates, and potassium. Plant materials require ethanol and water to provide a good extraction. (Note col. 4, lines 12-20).

Ericsson does not teach using a salt for purifying for extraction.

DD 202800 teaches plant extraction and purification using a NaCl solution. The solution is then dried. The reference teaches the method to yield high purity proteins. (Note abstract)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ericsson and DD. One would be motivated to do since DD teaches that the salt solution method yields high purity proteins from plant material. Further, Ericsson exemplifies extraction of essential oils from plant material and teaches that different solvents are used to extract different material from the natural source, as seen in the DD reference.

Claims 7 and 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericsson (5773241) in view of JP 359088065.

As set forth above, Ericsson discloses the method of preparing bioactive extracts. The method for animal tissue (organs or glands) involves macerating the tissue and adding a solvent containing NaCl, KCl, etc. For extracting proteins and alkaloids, the temperature of distillation should be low in order not to denature the active material. (Note col.4, lines 20-51).

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Ericsson does not teach using bones in the method of extraction.

JP teaches the immersing bone or marrow in sodium hypochlorite, adding aqueous solution of lecithin, mixing, grinding, and heating the mixture. The active substance is then dehydrated. This method produces a material rich in nutrients. (Note abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ericsson and JP 359088065. One would be motivated to do so if collagen is the desired active substance extracted since animal bone contains collagen and JP teaches obtaining proteins from a bone or marrow. Further, JP and Ericsson both teach the method of dehydrating active substances.

Conclusion

Any inquiry concerning this communication from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can be normally reached M-F from 7:30 am to 4:15pm.

If attempts to reach the examiner by the telephone are unsuccessful, the examiner's supervisor, Jose Dees, can be reached at (703) 308-4628. The fax number for this organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, whose telephone number is (703) 308-1235.

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SSG

[Signature]

May 3, 2002

[Signature]
JOSE G. DEES
SUPERVISORY PATENT EXAMINER
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